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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,434	12/12/2001	Mark K. Hechinger	1007-109.US	4955

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EXAMINER

YU, MELANIE J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,434

Applicant(s)

HECHINGER, MARK K.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
4a) Of the above claim(s) 1-5 and 12-15 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 6-11 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Applicant's amendment filed 16 June 2005 has been entered. Claims 6-11 are currently amended. Claims 1-5 and 11-15 have been withdrawn. Claims 1-15 are currently pending in this application.

Withdrawn Rejections

2. Previous rejection of claims 6-11 under 35 USC 112, second paragraph have been withdrawn.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 10 and 11, it is unclear whether the claims are drawn to an assay kit or an assay method. Claims 10 and 11 do not appear to provide product limitations to the assay kit of claim 6, and instead appear to claim a kit capable of performing a recited assay. It is therefore vague as to whether the assay kit or the assay method is claimed in rejected claims 10 and 11.

Claim Rejections - 35 USC § 103

4. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (US 5,286,452) in view of McHugh et al. (Clin. Imm., 1991), Ngo et al. (US 4,977,077), Victor et al. (US 5,573,911), and Schwartz et al. (US 5,380,663).

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Regarding claims 6-8, Hansen teaches the use of multiple-sized spherical latex particles either coated with or mixed with specific antigens or antibodies in order to detect multiple analytes from a sample. The particles range in size from 0.02 μm to 12 μm (col. 12, lines 35-68), which encompasses the recited 3, 4, 5, 6, 7 or 8 μm . Hansen also teaches buffer containing BSA may be used to block the non-specific binding sites on the beads (col. 13, line 67; col. 14, line 48). Hansen further teaches that the invention may be used with any known antigen-antibody combination and is not limited to its specific examples (col. 13, lines 13-30). However, Hansen fails to teach goat anti-human IgG F(ab')²-FITC, sodium carbonate, sodium bicarbonate, the antigens recited in rejected claim 6, and a kit.

McHugh et al. teach the use of microspheres that are less than 10 μm in diameter for multi-analyte assays. McHugh et al. teach the use of a label of fluorescein isothiocyanate conjugated to goat anti-human IgG or IgM in order to detect microspheres (pgs. 60-61). McHugh et al. also teach the use of multiple microspheres, each coated with a different antigen (pgs 62-63). However, McHugh et al. fail to teach sodium carbonate and sodium bicarbonate, the specific antigens of rejected claim 6 and a kit.

Ngo et al. teach an immunoassay, wherein beads are prepared for use as the solid phase of the immunoassay by rinsing in sodium bicarbonate solution, followed by immersing anti-drug antibody in sodium carbonate buffer (col. 7, lines 5-31), in order to prepare beads for use in an antibody binding assay. Ngo et al. fail to teach the specific antigens of the claims or a kit.

Victor et al. teach an immunoassay for the simultaneous detection of autoimmune antibodies to multiple antigens, such as SS-A, SS-B and Scl-70 grouped in predetermined combinations (col. 4, lines 53-63).

Schwartz et al. teach a kit comprising antibody-coated beads in order to use with a flow cytometer (col. 2, line 65-col. 3, line 8).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the beads/microspheres of Hansen et al., labels with fluorescein isothiocyanate conjugated to goat anti-human IgG as taught by McHugh et al., in order to provide a label with increased sensitivity and specificity.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the particles/microspheres of Hansen in view of McHugh et al., sodium carbonate and sodium bicarbonate as taught by Ngo et al., in order to provide buffers to aide in more effectively coating beads with receptors.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the particles/microspheres of Hansen in view of McHugh et al. and Ngo et al., detecting one or more of SS-A, SS-B and Scl-70 with their corresponding antibodies as taught by Victor et al., in order to provide disease diagnosis and monitoring of Systemic Lupus Erythematosus and Sjogren's Syndrome by detecting antinuclear antibodies and assess a patient's condition.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the particles/microspheres, buffers, antibodies and antigens of Hansen in view of McHugh et al., Ngo et al and Victor et al. in a kit as taught by Schwartz et al, in order to provide a convenient way to store all the required reagents for an assay together and increasing ease of use and efficient allocation of resources.

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With respect to claim 9, Hansen teaches latex beads that range in size from 0.02 μm to 12 μm (col. 12, lines 35-68), which encompasses the recited 3, 4, 5, 6, 7 or 8 μm , with different antibodies immobilized on each bead (col. 13, lines 13-30). Therefore by immobilizing the different antigens of Victor et al. on the different sized beads of Hansen, the bead size and antigen combinations recited in rejected claim 9 would be encompassed.

Claims 10 and 11 appear to be drawn to a kit used for simultaneous detection of anti-antibodies and specific assay steps. Additional product limitations do not appear to be required for the kit of claim 6. Furthermore, it is unclear what product limitations would be required for the recited assay method. Therefore the kit of Hansen in view of McHugh et al., Ngo et al., Victor et al., and Schwartz et al. would be capable of performing the recited assay and use of simultaneously detecting anti-antibodies because all product limitations required for the kit are taught.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of US Patent No. 6,159,748. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a fluorescent immuno-bead assay kit for detection of antinuclear antibodies comprising latex beads of similar sizes, the same antigens and antiantigens, goat anti-human IgG F(ab')²-[FITC], sodium carbonate, sodium bicarbonate, and bovine serum albumin, and one of ordinary skill in the art would realize that the two sets of claims read on each other.

Response to Arguments

1. With respect to applicant's amendment, previous rejection of claims 6-11 have been withdrawn. However, applicant's amendments to claims 10 and 11 have rendered claims 10 and 11 indefinite.

2. Applicant's arguments filed 16 June 2005 have been fully considered but they are not persuasive. At pages 14-16 Applicant argues that the process of Hansen utilizes the process of agglutination of beads while applicant discretely separates individual, single bead sizes. Applicant further argues that washing is required for the method of Hansen, and not required for the rejected claims. However, these limitations are not found in the rejected claims, and are further drawn to an assay method while the rejected claims are drawn to an assay kit. At page 18, applicant argues that the present invention uses size discrimination for separating each bead and then fluorescent markers to detect the presence or absence of the specific binding, which is not taught by Hansen. However, such a limitation is drawn to an assay method and is not encompassed by the rejected claims drawn to an assay kit. Applicant further argues that Hansen has limitations on the number of assays performed in one tube. However this feature is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

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limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

3. At pages 16-18, applicant argues that the instant invention requires a bicarbonate and carbonate specialized mixture that is not taught by McHugh. However, the rejected claims require only sodium carbonate and sodium bicarbonate, and do not specifically require a bicarbonate and carbonate specialized mixture. Applicant argues the instant invention does not require PBS-BSA-Tween to wash the beads as taught by McHugh, only a protein/bead incubation is required which is not taught by McHugh, and the instant invention does not need to store beads in solutions containing glycerol as taught by McHugh. However, these limitations are not specified in the rejected claims and are further drawn to method steps that are not encompassed by the assay kit recited in the rejected claims.

4. At page 19, applicant argues that Ngo counts the development of the supernatant in either radioactive counts of fluorescent intensity at a static state and Schwartz's beads are strictly fluorescent beads of different intensities used to calibrate flow cytometers. However, neither of these limitations are included in or excluded from the rejected claims. Furthermore, such limitations are drawn to methods and do not further limit the claimed product of an assay kit. Applicant further argues that Victor teaches a referencing technique that is neither a flow cytometric method. However, Victor is not relied upon for having a flow cytometric method and Schwartz is relied upon for having a kit compatible with a flow cytometric method.

5. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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09/06/05